# Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

## SERINGUES TROIS PIECES

| | | |
|---|---|---|
| **1. Renseignements administratifs concernant l'entreprise** | | ***Date de mise à jour : Septembre 2011*** |
| **1.1** | **Nom : TERUMO France** | |
| **1.2** | **Adresse complète :**<br>**Bât.Uranus**<br>**Rue Hélène Boucher, 1 Parc Ariane**<br>**78284 Guyancourt Cedex** | **Tel: 01 30 96 13 00 Fax : 01 30 43 60 85**<br>**e-mail : terumo.france@terumo-europe.com**<br>**Site internet : www.terumo-europe.com** |
| **1.3** | **Coordonnées du correspondant matériovigilance :**<br>**Sébastien RENARD** | **Tel : 01 30 96 13 03**<br>**Fax : 01 30 43 60 85**<br>**e-mail : sebastien.renard@terumo-europe.com** |
| **2. Informations sur le dispositif ou équipement** | | |
| **2.1** | **Dénomination commune : selon la nomenclature d'Europharmat® Seringue** | |
| **2.2** | **Dénomination commerciale: Seringue trois pièces** | |
| **2.3** | **Code nomenclature : Code GMDN : 13940**<br>**Code CLADIMED :** | |
| **2.4** | **Code LPP* : Non applicable**<br>* « liste des produits et prestations remboursables » inscrits sur la liste prévue à l'article L 165-1 | |
| **2.5** | **Classe du DM : IIa**<br>**Directive de l'UE applicable : 93/42 révisée 2007-47 Selon Annexe n° II et V**<br>**Numéro de l'organisme notifié : CE 0197 (TÜV Rheinland, Cologne Allemagne)**<br>**Date de première mise sur le marché dans l'UE : Avant 1998**<br>**Fabricant du DM : Terumo Belgique, Terumo Japon, Terumo Philippines** | |
| **2.6** | **Descriptif du dispositif (avec photo, schéma, dimensions, volume, …) :**<br><br>Seringues trois pièces, stériles.<br>Seringue destinée à l'injection de médicaments, immédiatement après leur préparation.<br><br>Insertion photos : relié au point 9<br><br> | |

**2.7** **Références Catalogue** :

**Tableau des références**

| Références | Volume | Description | Nbre Unit/boîte | Nbre unit/carton |
|---|---|---|---|---|
| **8SS01T1*** | 1ml | Embout centré | 100 | 1800 |
| **8SS01H1**** | 1ml | Embout centré | 100 | 1800 |
| **2SS02S** | 2,5ml | Embout centré | 100 | 1200 |
| **1SS05SE1** | 5ml | Embout centré | 100 | 1600 |
| **2SS10ES** | 10ml | Embout excentré | 100 | 500 |
| **8SS20ES1** | 20ml | Embout excentré | 50 | 600 |
| **1SS30ESE1** | 30ml | Embout excentré | 50 | 400 |
| **2BS50ES** | 50ml | Embout excentré | 25 | 100 |
| **2BS50C** | 50ml | Embout cathéter | 25 | 100 |

*= seringue à tuberculine **= seringue à insuline

**Conditionnement/Emballages:**

**UCD (Unité de commande): 25, 50 ou 100 seringues selon le volume**

**CDT (Multiple de l'UCD): Quantité variable selon le volume voir tableau ci dessus**

**QML (Quantité minimale de livraison) : Le carton**

**Code à barres : EAN 128**

**Descriptif de la référence:**

| POSITIONS | REFERENCES | EXPLICATIONS |
|---|---|---|
| 1 | **1, 2, 8** | Lieu de fabrication : **1**=Japon, **2**=Belgique et **8**=Philippines |
| 2-3 | **SS/BS** | Seringue |
| 4-5 | **01, 02, 05, 10, 20, 30, 50** | Volume en ml : **01**=1ml **02**=2ml **05**=5ml **10**=10ml **20**=20ml **30**=30ml **50**=50ml |
| 6-7 | **T, H, S, C, ES** | **T**= Tuberculine<br>**H**= Insuline<br>**C**= Embout cathéter<br>**ES**= Embout excentré<br>**S**= Embout centré |
| 8-9 | **E1 ou 1** | Stérilisation aux rayons β |

**Etiquetage** : Voir ANNEXES

**2.8** **Composition du dispositif et Accessoires : pour chaque élément ou composant, précisé :**

| Eléments | Matériaux |
|---|---|
| Corps | Polypropylène |
| Piston | Polystyrène |
| Joint | Elastomère thermoplastique |
| Lubrifiant | Huile de silicone |

**Pour les composants susceptibles d'entrer en contact avec le patient et/ou les produits administrés, précisions complémentaires:**

- ✓ **Absence de Latex**
- ✓ **Absence de produit d'origine animale ou biologique**
- ✓ **Absence de PVC**

**Toutes mentions jugées utiles pour les précautions d'utilisation :**

- ➢ **Vérifier l'intégrité du protecteur individuel de stérilité avant utilisation**
- ➢ **Strict usage unique**
- ➢ **Eliminer de façon sécuritaire afin d'éviter le risque de contamination**

**2.9** **Domaine - Indications :**

Domaine d'utilisation (selon liste Europharmat) : **Injection**
Indications (selon liste Europharmat): **Injection ou prélèvement**

# Dossier d'information Euro Pharmat

## DISPOSITIF MEDICAL

| | |
|---|---|
| **3. Procédé de stérilisation :** | |
| | **DM stérile:** **OUI**<br>**Mode de stérilisation du dispositif : Stérilisé à l'Oxyde d'éthylène, validation du process selon la norme EN ISO 11135-1:2007**<br>**Pour références avec un 1 ou un 8 : stérilisation par rayonnement β selon la norme EN ISO 11137-1:2006/11137-2:2007** |
| **4. Conditions de conservation et de stockage** | |
| | Conditions normales de conservation & de stockage<br>précautions particulières:<br>**- Eviter le stockage à des températures excessives et à l'humidité**<br>Durée de la validité du produit: **5 ans**<br>Présence d'indicateurs de température s'il y a lieu: **Non** |
| **5. Sécurité d'utilisation** | |
| **5.1** | **Sécurité technique** : |
| **5.2** | **Sécurité biologique (s'il y a lieu) : Non applicable** |

| | |
|---|---|
| **6.** Conseils d'utilisation | |
| 6.1 | Mode d'emploi : |
| 6.2 | Indications : |
| 6.3 | Précautions d'emploi : Voir mentions jugées utiles ci dessus |
| 6.4 | Contre- Indications : |
| **7.** Informations complémentaires sur le produit | |
| | Bibliographie, rapport d'essais cliniques, ou d'études pharmaco-économiques, amélioration du service rendu : recommandations particulières d'utilisation (restrictions de prise en charge, plateau technique, qualification de l'opérateur, etc) … : |
| **8.** Liste des annexes au dossier (s'il y a lieu) | |
| | ✓ Précautions d'emploi sur la boite (Annexe 1)<br>✓ Boîte (Annexes 2)<br>✓ Certificat de marquage CE Belgique + déclaration de conformité (Annexe 3 et 3-1)<br>✓ Certificat de marquage CE Philippines + déclaration de conformité (Annexe 4 et 4-1)<br>✓ Certificat de marquage CE Japon + déclaration de conformité (Annexe 5 et 5-1) |
| **9. Images (s'il y a lieu)** | |
| | Format gif, jpeg, png |

## ANNEXE 1

**Précautions d'emploi boite**

## ANNEXE 2

**Boite**

TERUMO®
CE 0197
TERUMO® SYRINGE
SERINGUE / SPRITZE / JERINGA / SIRINGA / SPUIT / SPRUTA
LATEX FREE / SANS LATEX / LATEXFREI / SIN LATEX /
PRIVA DI LATTICE / LATEX-VRIJ / LATEX FRI
ECCENTRIC
50 UNITS / UNITES
STÜCK / UNIDADES
UNITÀ / STUKS
STYCK
30 mL

**ANNEXE 3**

TÜVRheinland®

## APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60035711 0001

Report No.: 21150638 001

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Design/Development and Manufacturing of Medical Devices

(see attachment for products and additional sites included)

Replaces Approval, Registration No.: HD 60024159 0001

Date of Expiry: 07.12.2015

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 08.12.2010

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland®

Doc. 1/2, Rev. 0

**TÜV Rheinland**
**LGA Products GmbH**
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**
**Registration No.:** HD 60035711 0001
**Report No.:** 21150638 001

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Products:

- Syringes
- Needles
- Administration sets
- Blood collecting systems
- Short peripheral catheters and related accessories
- Angiographic- interventional catheter systems
- Extra corporeal circuits for open heart surgery
- Non-vascular guide wires
- Transfusion Systems

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Ancillary devices for extracorporeal circuits for open heart surgery
- Blood collecting systems
- Syringes for oral/enteral use

Certification Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date 08.12.2010

Dipl.-Ing. D. Meier

TÜVRheinland®

Doc. 2/2, Rev. 0

**TÜV Rheinland**
**LGA Products GmbH**
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**
**Registration No.:** HD 60035711 0001
Report No.: 21150638 001

Manufacturer: TERUMO EUROPE N.V.
Interleuvenlaan 40
3001 Leuven
Belgium

Scope: Sites included:

TERUMO EUROPE N.V.
European Distribution Center
Brikkenovenstraat 48
3600 Genk, Belgium
Scope: Warehouse operations of medical devices

TERUMO UK
3 Unity Grove, off School Lane,
Knowsley Industrial Park South, Knowsley,
Merseyside L34 9GT, United Kingdom
Scope: Design/development and manufacture of extracorporeal circuits for open heart surgery and ancillary circuits

Certification Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date 08.12.2010

Dipl.-Ing. D. Meier

**ANNEXE 3-1**

TERUMO

Rev. 19
PS-3009

## DECLARATION OF CONFORMITY

We, **TERUMO EUROPE N.V.**
**Interleuvenlaan 40,**
**3001 Leuven, Belgium**

being the manufacturer of:

**TERUMO® SYRINGE WITHOUT NEEDLE**
**TERUMO® SYRINGE WITH NEEDLE**

**Product:** Hypodermic Syringes for manual use
(See Appendix A for related product codes)

declare that the above products of Class IIa are in conformity with the provisions of the EC Council Directive 93/42/EEC of 14 June 1993 as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11.2 and 11.3(a) of the Directive, relating to the "Full Quality Assurance System" set out in Annex II, and by certification of Annex II.3, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No: HD 60035711 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Leuven, 17 August 2011
(place and date of issue)

M.J. AERTS
Manager Regulatory Affairs
TERUMO EUROPE N.V.

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TERUMO

Rev. 19

PS-3009

## Appendix A – Related product codes

The product code is composed of 12 digits maximum and explained as follows:

**Product code syringes without needle:**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| B | S | Blister Syringes | | | | | | | | | |
| S | S | Blister Syringes new design | | | | | | | | | |
| Production site | | - | Terumo Europe N.V. | | | | | | | | |
| Product item | | | 0 | 1 | 1 ml Luer | | | | | | |
| | | | G | 2 | 2 ml | | | | | | |
| | | | 0 | 2 | 2.5 ml | | | | | | |
| | | | 1 | 0 | 10 ml | | | | | | |
| | | | 5 | 0 | 50 ml | | | | | | |
| Item type | | | | | T | | Tuberculin | | | | |
| | | | | | S | | Center Luer Slip Tip | | | | |
| | | | | | E | S | Eccentric Luer Slip Tip | | | | |
| | | | | | C | | Catheter tip | | | | |
| Alphanumerical indication to distinguish from standard items | | | | | | | | | | | |

**Product code syringes with needle:**

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| B | S | Blister Syringes | | | | | | | | | |
| S | S | Blister Syringes new design | | | | | | | | | |
| Production site | | - | Terumo Europe N.V. | | | | | | | | |
| Product item | | | 0 | 1 | 1 ml Luer | | | | | | |
| | | | 0 | 2 | 2.5 ml | | | | | | |
| | | | 1 | 0 | 10 ml | | | | | | |
| Item type | | | | | T | Tuberculin | | | | | |
| | | | | | S | Center Luer Slip Tip | | | | | |
| Cannula size | | | | | | 2 | 0 | 20 G (0.9 mm) | | | |
| | | | | | | 2 | 1 | 21 G (0.8 mm) | | | |
| | | | | | | 2 | 2 | 22 G (0.7 mm) | | | |
| | | | | | | 2 | 3 | 23 G (0.6 mm) | | | |
| | | | | | | 2 | 5 | 25 G (0.5 mm) | | | |
| | | | | | | 2 | 6 | 26 G (0.45 mm) | | | |
| Needle length | | | | | | | | 1 | 3 | 12 mm = 1/2" | |
| | | | | | | | | 1 | 6 | 16 mm = 5/8" | |
| | | | | | | | | 2 | 5 | 25 mm = 1" | |
| | | | | | | | | 3 | 2 | 30 mm = 1-1/4" | |
| | | | | | | | | 3 | 8 | 40 mm = 1-1/2" | |
| Alphanumerical digits to distinguish from standard items | | | | | | | | | | | |

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TERUMO

Rev. 19

PS-3009

Product code syringes provided with more than one needle:

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| S | S | Blister Syringes new design | | | | | | | | | |
| Production site | | - | Terumo Europe N.V. | | | | | | | | |
| Product item | | | 0 | 2 | 2.5 ml | | | | | | |
| Item type | | | | | S | Center Luer Slip Tip | | | | | |
| Cannula size (1) | | | | | | 1 | 8 | 18 G (1.2 mm) | | | |
| Cannula size (2) | | | | | | | | 2 | 1 | 21 G (= 0.8 mm) | |
| Cannula size (3) | | | | | | | | 23 G (= 0.6 mm) | | 2 | 3 |

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**ANNEXE 4**

TÜVRheinland®

## APPROVAL

EC Directive 93/42/EEC Annex V, Article 3
Quality Assurance System Production

Registration No.: DD 60038153 0001

Report No.: 60013826 003

Manufacturer: Terumo (Philippines) Corporation
124 East Main Avenue
Laguna Technopark
Binan, Laguna,
Philippines

Scope: Manufacture of Disposable Sterile Medical Devices

(See attachment for products included)

Replaces Approval, Registration No.: DD 60029244 0001

Date of Expiry: 11.02.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 08.03.2011

Dipl.-Ing. O. Masur

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜVRheinland®

Doc. 2/2, Rev. 0

**TÜV Rheinland**
**LGA Products GmbH**
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**
**Registration No.:** DD 60038153 0001
**Report No.:** 60013826 003

Manufacturer: Terumo (Philippines) Corporation
124 East Main Avenue
Laguna Technopark
Binan, Laguna,
Philippines

Scope: Aspects of manufacture concerned with securing and maintaining sterile conditions

- Syringes without Needles
- Urinary Drainage Bags
- Syringes for Oral/Enteral

Sterilization Method:
Irradiation using Electron Beam

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Certification Body

Date 08.03.2011

Dipl.-Ing. O. Masur

TÜVRheinland

Doc. 1/2, Rev. 0

**TÜV Rheinland**
**LGA Products GmbH**
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**
**Registration No.:** **DD 60038153 0001**
Report No.: 60013826 003

Manufacturer: Terumo (Philippines) Corporation
124 East Main Avenue
Laguna Technopark
Binan, Laguna,
Philippines

Scope: Products included:

- Syringes with Needles
- Intravenous Catheter
- Safety Needles
- Syringes with Safety Needles

Sterilization Method:
Irradiation using Electron Beam

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Certification Body

Date 08.03.2011

Dipl.-Ing. O. Masur

**ANNEXE 4-1**

TERUMO

TERUMO (PHILIPPINES) CORPORATION
124 East Main Ave., Laguna Technopark, Biñan, Laguna, Philippines
Tel. No. (049) 541-2111 • Fax No. (049) 541-2121

## DECLARATION OF CONFORMITY

| | |
|---|---|
| **Name and Address** | Terumo (Philippines) Corporation<br>124 East Main Avenue, Laguna Technopark<br>Binan, Laguna, Philippines |

We declare under our sole responsibility that the

| | | | | |
|---|---|---|---|---|
| Medical Device | Terumo Syringe without Needle | | | |
| Product Code | SS+01T | SS+05L1 | SS+10S | SS+20SM |
| | SS+01TM | SS+05L6 | SS+10S6 | SS+20ES |
| | SS+01T6 | SS+05LM | SS+10ES | SS+20ES6 |
| | SS+03L | SS+05S | SS+10ESM | SS+20ES1 |
| | SS+03L1 | SS+05S6 | SS+20L | SS+20ESM |
| | SS+03LM | SS+10L | SS+20L1 | SS+30L1 |
| | SS+03L6 | SS+10L1 | SS+20LN | SS+60C |
| | SS+03S | SS+10L6 | SS+20LM | SS+60CM |
| | SS+03S6 | SS+10LM | SS+20S | SS+01NA |
| | SS+05L | SS+01T1 | SS+01H1 | |

| | |
|---|---|
| Of Class | Class IIa, Rule 2 Annex IX of MDD |

meets all the provisions of the Directive 93/42/EEC as amended which apply to it.

| | | |
|---|---|---|
| **Applied harmonized standards, national standards or other normative documents** | EN 556-1:2001 | ISO 10993-11:2006 |
| | ~~EN ISO 14971:2009~~ | ~~ISO 7886-2:1996~~ |
| | EN 980:2008 | ISO 7886-1:1993 Cor1:1995 |
| | EN 1041:2008 | EN ISO 11137-1:2006 |
| | EN ISO 11607-1:2009 | EN ISO 11137-2:2007 |
| | EN ISO 11607-2:2006 | ISO 11137-3:2006 |
| | ISO 14644-1:1999 | ISO 594-1:1986 |
| | ISO 14644-2:2000 | ISO 594-2:1998 |
| | EN ISO 10993-1:2009 | ISO 11737-1:2006 |
| | ISO 10993-4:2002 Amd 1:2006 | ISO 11737-2:2009 |
| | ISO 10993-5:2009 | ISO 8537:2007 |
| | ISO 10993-10:2010 | |

| | |
|---|---|
| **Conformity Assessment Procedure** | MDD 93/42/EEC as amended, Annex VII combined with the provisions set out in Annex V "Production Quality Assurance" |

Terumo Syringe
PQB-SS003

rev.16

# Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

| | |
|---|---|
| **Notified Body** | TUV Rheinland LGA Products GmbH (Registration No. DD 60038153 0001), authorized by the German Competent Authority and carrying the Notified Body No. 0197 |
| **Address** | Tillystrasse 2, 90431 Nurnberg, Germany |

Philippines, 9/8/11

**Place, Date of Issuance**

Bernie Salvador

**Manager/Quality Assurance**

Terumo Syringe
PQB-SS003

rev.16

**ANNEXE 5**

TÜVRheinland®

## APPROVAL

**EC Directive 93/42/EEC Annex II, Article 3**
**Full Quality Assurance System**
**Medical Devices**

**Registration No.:** HD 60026344 0001

**Report No.:** 12018114 001

**Manufacturer:** Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

**Scope:** Design/Development and Manufacture of Medical Devices

(see attachement for products included)

Replaces Approval, Registration No.: HD 60012340 0001

**Date of Expiry:** 12.08.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

TÜV Rheinland Product Safety GmbH Zertifizierungsstelle

Cologne, 07.09.2009

Dr. H. Lüdemann

**TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln**
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

# Dossier d'information Euro Pharmat

DISPOSITIF MEDICAL

TÜVRheinland®

Doc. 1/2, Rev. 1

**TÜV Rheinland**
**LGA Products GmbH**
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**
**Registration No.:** HD 60026344 0001
Report No.: 12018114 003

Manufacturer: Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

Scope: Products included:
- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter

- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Spinal Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

Certification Body

Date 21.04.2011

Dipl.-Ing. D. Meier

TÜVRheinland

Doc. 2/2, Rev. 1

**TÜV Rheinland**
**LGA Products GmbH**
**Tillystraße 2, 90431 Nürnberg**

**Attachment to**
**Registration No.:** HD 60026344 0001
**Report No.:** 12018114 003

Manufacturer:
Terumo Corporation
44-1, 2-chome, Hatagaya
SHIBUYA-KU,TOKYO 151-0072
JAPAN

Scope:

Products included:
Extra-corporeal Membrane Oxygenator
Cardiopulmonary Bypass Arterial Line Blood Filter
Heart-Lung Bypass Defoamer
Cardiotomy Reservoir
Cardiopulmonary Bypass Blood Reservoir
Haemoconcentration Filter
Centrifugal Pump
Angiographic Catheter
Balloon Dilatation Catheter
Catheter Guide Wire
Guiding Catheter
Catheter Introducer
Stents
Epidural Anesthesia Kit
Extension Tube
Temperature Control Unit for Heart-Lung Bypass System Module
Infusion Pump
Syringe Infusion Pump
Clinical Electronic Thermometer
Clinical Electronic Blood-Pressure Monitor
Endoscopic Electromechanical Surgical Systems

Certification Body

TÜVRheinland Zertifizierungsstelle

Date 21.04.2011

Dipl.-Ing. D. Meier

**ANNEXE 5-1**

No.DOC-PQB-TF-SS

Rev.05

## DECLARATION OF CONFORMITY

We, **TERUMO CORPORATION**
**44-1, 2-chome, Hatagaya, Shibuya-ku, Tokyo 151-0072, Japan**

being the manufacturer of:

**TERUMO Syringe**

Product : Hypodermic Syringe

declare that the above products of **Class IIa** are in conformity with the provisions of Annex I and Annex II of the EC Council Directive 93/42/EEC of 14 June 1993, as amended, concerning medical devices, and have been subject to the conformity assessment procedure laid down in Article 11, 3(a) of the Directive, relating to the "Full quality assurance" set out in Annex II, under the supervision of TÜV Rheinland LGA Products GmbH (Registration No.: HD 60026344 0001), as Notified Body authorized by the German Competent Authority and carrying the Notified Body No. 0197.

Authorized European Representative :
TERUMO EUROPE N.V.
Interleuvenlaan 40, 3001 Leuven, Belgium

Object of the declaration: see appendix A

Tokyo, March 21, 2010
(place and date of issue)

H. Nakagomi
Hiroshi Nakagomi
General Manager
Quality Assurance Department
TERUMO CORPORATION

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## Appendix A - List of Code Number Structure

S S □ □ □ □ □ □ or
1 2 3 4 5 7

S S □ □ □ □ □ or
1 2 3 4 5

S S □ □ □ □ □ ○ ○ ○ ○ △
1 2 3 4 5 6 7

1. Product series (product type) (one digit)
   SS : Syringe
2. Destination (Japan and overseas) (two digits)
   - : Japan ＊ : Overseas
3. Nominal capacity (product type) (two digits)
   02 : 2.5mL
   05 : 5mL
   10 : 10mL
   20 : 20mL
   30 : 30mL
   50 : 50mL
4. Cylinder head shape (one or two digits)
   S : Slip tip
   L : Round lock
   ES : Cross slip tip
   C : Catheter tip
5. Others
   Z : Gamma sterilization
   E : Electron beam sterilization
6. Injection needle type (four digits)
   Upper two digits : Needle gauge
   Lower two digits : Needle length
7. Last digit
   1 : CE display

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